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EXAMINER

LEARY, LOUISE N

ART UNIT PAPER NUMBER

1654

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/721,031

Applicant(s)

PARSONS ET AL.

Examiner

Louise N. Leary

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-106 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-106 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/23&8/25/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

1. Claims 1-106 are pending in this application.

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-51 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-51 of copending Application No. 10/620,475. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-106 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Burnett et al (US 6407211, 6-18-2002).

Burnett et al disclose liquid formulations comprising Dendroaspis natriuretic peptides and methods of using the peptides. Burnett et al disclose natriuretic peptides formulations comprising a pharmaceutically acceptable carrier, a diluent, hydrochloric acid, acetic acid, sodium hydroxide. Thus, the Burnett et al disclosure addresses the phrase “a stable liquid calibrator or control” because Burnett et al disclose the use of each of the different types of ingredients in the calibrators or controls set forth in the instant claims. See this entire document. With respect to the proteins or polymer in instant claims 11-13, Burnett et al disclose natriuretic pharmaceutical formulations comprising amino acids or milks or gels and/or natriuretic peptides formulations comprising polyethylene glycols. See pages 19-26. Burnett et al discloses or suggests using various combinations of the natriuretic peptides in various pharmaceutical formulations. In addition, Burnett et al disclose or suggest how to make natriuretic peptide pharmaceutical formulations. Note this entire document. With respect to the instantly claimed “stable test sample” and “method of making the stable test sample”, Burnett et al disclose test samples comprising diluent in the percentage range of “about 20% to 90% (v/v). See especially pages 24-25. Thus, Burnett et al disclose the invention claimed except for addressing the claimed pH ranges.

However, regarding the pH ranges claimed in the instant invention, Burnett et al disclose liquid natriuretic peptide formulations comprising Dendroaspis natriuretic or at least one other natriuretic peptide, a buffer, an acid, and a base which would inherently exhibit a pH value

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within the pH ranges claimed in the present invention. Burnett et al also disclose or suggest methods for making natriuretic peptides, test samples and methods of making the test samples using reactants and reaction conditions within the scope of the instant claims which anticipates or renders obvious the present invention.

The burden of proof is on applicants to show patentably distinct differences between the Burnett et al disclosure and the invention claimed herein.

4. The Chang et al reference discloses "compositions and methods for the synthesis of natriuretic protein receptor B and methods of use" and has been cited to further show the state of this art.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (571)272-0966. The examiner can normally be reached on Monday to Friday from 9:30 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Louise N. Leary
Primary Examiner
Art Unit 1654
December 11, 2004